

### REMARKS

Claims 1-17 are pending in the present applications. Applicants have carefully studied the outstanding Office Action. The present Response is intended to be fully responsive to all points of rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of this application are respectfully requested. No new matter has been added by any of the amendments to the specification. Applicants respectfully request reconsideration and withdrawal of the Examiner's rejections in view of the foregoing amendments and following remarks.

### **CLAIM REJECTIONS – 35 U.S.C. § 103**

The Examiner has rejected claims 1-17 under 35 U.S.C. § 103(a) as being unpatentable over Wright (Alternative Medicine, Townsend Letter for Doctors & Patients, July, 1999, pages 2-3); Kumar et al. (Indian Journal of Medical Research, 1982, 76 (suppl.), pages 46-53; see English abstract) newly cited, Carella et al (WO 97/29763) and Iwahi et al. (J. Med. Microbol., 1982, 15(3), 303-316 of record. After stating the factual inquiries required by *Graham* in determining the obviousness of an invention under 35 U.S.C. §103(a), the Examiner stated:

Wright teaches the use of D-Mannose for the treatment of urinary tract infections (page 96, left column, 4th paragraph; middle column, 3rd and 4th paragraphs; right column, first full paragraph). The dosage is one teaspoon, approximately 1-2.5 g, in the form of a powder dissolved in water, every three to four hours (page 96 right column, last paragraph and page 98, left column, first paragraph). However, Wright does not teach the treatment of urinary tract infections by administration of D-mannose powder directly or in combination with other extracts and compositions comprising D-Mannose and the extracts as instantly claimed.

Kumar et al. drawn to *crataeva nurvala*, teach that it is highly reputed for its therapeutic value in the treatment of urinary tract infections (see English abstract). However, Kumar et al do not suggest the combination of D-mannose and *crataeva nurvala* for the treatment of urinary tract infections. In addition to urinary tract infections other urinary disorders can also be treated by using *crataeva nurvala*.

Carella et al. teach the use of D-mannose in a composition for the promotion of a healthy environment in urogenital tracts and for treating urogenital disorders (page 2, lines 7-10 and 16-17; page 5, lines 15-16). Plant extracts (interpreted as herbs that affect urinary tract, as instantly claimed in claim 5) are also included in the composition (page 8, lines 23-27). The compositions can be administered as tablets, capsules (page 10, lines 7-10) and can contain 5 to about 75% per unit dose (page 6, lines 22-25). According to Carella additional ingredients and dosages can be readily ascertained using routine experimentation (page 14, lines 32-35). This means that the art recognizes that the dosages can be varied or frequency of administration adjusted till symptoms subside.

Iwahi et al. teach that d-mannose is potent in inhibiting viral adhesion to the urinary tract (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer d-mannose containing the herbal extracts as instantly claimed, to treat urinary tract infection since the use of mannose and the said herbal extracts like *crataeva nurvala* for the said treatment is seen to be taught in the prior art. One of ordinary skill in the art would be motivated to

use d-mannose and pollen extract and extracts of crataeva nurvala and willow bark as the active agents since d-mannose is potent in preventing viral adhesions to the urinary tract as taught by Iwahi et al and the extracts of pollen, crataeva nurvala and willow bark have additional benefits as taught by Kumar. It has been held that it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980. It is well within the purview of one of ordinary skill in the art to include other herbal extracts known for treatment of urinary tract infections and also adjust the administration dosage and the amounts in the compositions as instantly claimed in order to get the maximum beneficial effects of the active agents.

This rejection is respectfully traversed. The prior art cited by Examiner does not, either alone or in combination, teach or disclose every element of Applicants' invention. While all of the referenced prior art generally disclose the use of D-Mannose in the treatment of urinary tract infections, none of the prior art references teach the dosage and course of treatment requirements taught in the claims of the present invention. Moreover, the dosage and course of treatments disclosed in the cited prior art is in line with the prior art methods discussed and distinguished from in the specification of the subject application (see page 7, lines 2-12).

Absent any specific identification of the aforementioned dosage or course of treatments being taught or suggested in the Wright ©1999 Article, Kumar et al. Carella et al., or Iwahi, the aforementioned claims are nonobvious under 35 U.S.C. § 103. The Examiner has the burden of establishing a *prima facie* case of obviousness. Moreover, the Examiner is required to show that the referenced teachings "appear to have suggested the claim subject matter." *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143, 147 (C.C.P.A. 1976). As stated by the Federal Circuit, "Obviousness cannot be established by combining teachings of the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination." *In re Geiger*, 815 F.2d 683, 2 USPQ 2d 1276, 1278 (Fed. Cir. 1987). It is incorrect, therefore, for Examiner to formulate the suggestion or motivation based on current knowledge. Examiner must remove all knowledge that he has accumulated since the date of the invention. See, *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1 USPQ 2d 1593, 1595-96 (Fed. Cir. 1987). Examiner's failure to do so in this case is particularly telling when the primary reference cited against Applicants, is an article detailing Applicants' own initial research.

It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that "One cannot

use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.”

*In re Fritch*, 972 F.2d 1263, 23 USPQ 2d 1780, 1784 (Fed. Cir. 1992) (citation omitted).

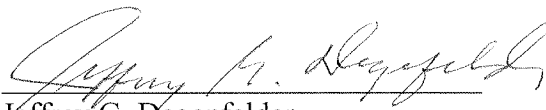
A general statement that “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to administer d-mannose containing the herbal extracts as instantly claimed ... is seen to be taught in the prior art” does not establish a *prima facie* case of obviousness. To modify the treatments disclosed in the Wright ©1999 Article, Kumar et al. Carella et al., or Iwahi, to include the dosage and course of treatment requirements taught in the claims of the present invention can only be achieved with the use of impermissible hindsight. As such, the rejection is improper because the claims are not rendered obvious for the reasons stated above. Examiner has not established a *prima facie* case of obviousness, and the rejection of claims 1-17 should be withdrawn.

**CONCLUSION**

Applicants believe the claims are in condition for allowance. It is respectfully urged that the subject application is patentable over references cited by Examiner and is now in condition for allowance. Applicants request consideration of the application and allowance of the claims. If there are any outstanding issues that the Examiner feels may be resolved by way of a telephone conference, the Examiner is cordially invited to contact David W. Carstens at 972.367.2001.

The Commissioner is hereby authorized to charge any additional payments that may be due for additional claims to Deposit Account 50-0392.

Respectfully submitted,

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